

REMARKS

I. Nature of the Office Action

With regard to the Office Action dated February 6, 2003, Applicants did not understand many of the comments made by the Examiner in support of the rejections. Even if Applicants understood certain comments, Applicants often saw no connection between the comments and the requirements for patentability that the Examiner was trying to assert. For example, the Examiner mentions at page 7 of the Office Action that "[r]esearchers often spend their entire life on hetero N heterocyclic compounds, without ever getting to hetero O or hetero S compounds." Even if this were true, Applicants see no reason why this relates to the patentability of the invention. Applicants are equally at a loss to respond to the Examiner's comments about interference counts.

In light of the above, it has been difficult for Applicants to fully and thoroughly respond to all concerns the Examiner might have. In the event that the Examiner maintains rejections in this case after considering this amendment, Applicants respectfully request that the Examiner not make the next action final. To the extent that any future Office Action may offer more clarity as to the bases for the rejections, Applicants should have the opportunity to address these issues without being bound to the restrictions imposed by a Final Office Action.

II. Status of the claims

After entering this amendment claims 1-8, 11-15, and 18-26 are pending in this application. The Examiner has withdrawn claims 11, 12, 18, 19, 22, and 23 from consideration. Claims 1 and 22 have been amended with the sole purpose of

expediting prosecution. Claim 7 has been amended in order to more clearly define the invention. Applicants reserve the right to pursue protection in subsequent continuation or divisional applications, or at a later stage of prosecution, for any subject matter that is not now claimed. Support for the amendments to claims 1 and 22 regarding the definition of heteroaryl can be found in the specification at p. 8, lines 26-32. Support for the amendment to claim 7 can be found in originally-filed claim 7. Support for new claims 24-26 can be found in originally-filed claim 12 and in the specification at p. 16, line 33 to p. 17, line 6.

III. Information Disclosure Statement

The Examiner returned the PTO 1449 forms Applicants submitted with the Information Disclosure Statement filed on February 13, 2001. However, the Examiner did not initial several abstracts listed on pages 4 and 5 of the 1449 form, apparently because no date was listed on the 1449 form for these references. The Examiner did initial the non-English language documents to which the Abstracts related. Applicants, therefore, acknowledge that the Examiner has considered those non-English language documents. Applicants respectfully request that the Examiner initial the Abstracts listed on the 1449 Form. The publication date is listed on the face of each abstract and on each patent application. For the Examiner's convenience, Applicants provide the publication dates of the references not initialed by the Examiner.

Japanese Patent Application Publication No. 06192252, published on July 12, 1994.

European Patent No. 0 136 976, published on April 10, 1985.

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German Patent Application No. 19744027, published on April 8, 1999.

German Patent Application No. 4034762, published on May 7, 1992.

German Patent Application No. 19756388, published on June 24, 1999.

Applicants respectfully request that the Examiner initial and return the aforementioned PTO 1449 form to Applicants. A copy of the aforementioned Information Disclosure Statement is also enclosed for the Examiner's convenience.

IV. Rejections under 35 U.S.C. § 112

The Examiner rejected claim 1 under 35 U.S.C. 112, 1st and 2nd paragraphs allegedly because the definition of heteroaryl in the claim is indefinite and the specification does not provide enough support for the "breath of the [claim's heteroaryl] expression." The Examiner rejected claims 2-8, 12, 15, 20, and 21 as being dependent on a rejected claim. Applicants respectfully traverse this rejection.

The Examiner argues that the number of atoms in the heteroaryl radical of claim 1 is open ended because the definition recites "one or more" heteroatoms. The Examiner further argues that "[t]he heteroaryl term is not set forth in clear, specific language" and that the term heteroaryl "reads on heterocyclic rings that require specific conception by the reader."

Applicants continue to maintain that the term heteroaryl in the claims is definite and supported by the specification for the reasons of record. However, with the sole purpose of expediting prosecution, Applicants have amended claims 1 and 22 indicating that the heteroaryl radical can have only one or two heteroatoms. Applicants reserve the right to pursue protection in subsequent continuation or divisional applications, or at

a later stage of prosecution, for any subject matter that is not now claimed. Furthermore, the term heteroaryl in the present claims is drawn to 5- or 6- membered **aromatic** monocyclic heterocycles, or to 8- to 10-membered **aromatic** bicyclic heterocycles. That is, the heteroaryl radical in the current claims is aromatic and not just any alicyclic heterocycle as the Examiner's comments throughout the Office Action seem to imply. The Office Action asked in several instances where the specification provides written description support for the term "heteroaryl." Applicants direct the Examiner's attention to page 8, line 26 to page 9, line 20.

The Examiner argues that heteroaryl radicals with "[a]djacent O and S are too strained to be produced." The Examiner further argues that "Applicants should not be permitted to pre-empt future work of others. Someone may find a way to reduce the strain between adjacent hetero atoms in a ring by changing the bond angles to make the compound, only to find applicants already claimed it here, but never made it." Applicants have repeatedly responded to this rejection without receiving a response from the Examiner to any of Applicants' arguments in this regard. Applicants have brought to the Examiner's attention case law indicating that claims are not indefinite when the skilled artisan is able to discern the non-operative embodiments of the claim. For Example, the Examiner has been reminded that even if a claim encompasses inoperative embodiments, the presence of such embodiments does not necessarily constitute a proper basis for rejection. *See e.g. In re Dihn-Nguyen*, 492 F. 2d 856, 858-59 (C.C.P.A 1974) (holding that "[e]ven if some of the claimed combinations were inoperative, the claims are not necessarily invalid.") The deciding factor in this determination is whether the skilled artisan would be able to recognize and avoid such

inoperative embodiments. In this respect, the following quotation of the court in *In re Cook* is on point:

[M]any patented claims read on vast numbers of inoperative embodiments in the trivial sense that they can, and do, omit 'factors which must be presumed to be within the level of ordinary skill in the art,' and therefore read on embodiments in which such factors *may* be included in such a manner as to make the embodiments inoperative. There is nothing wrong with this so long as it would be obvious to one of ordinary skill in the relevant art how to include those factors in such manner as to make the embodiment operative rather than inoperative.

In re Cook, 439 F. 2d 730,735 (C.C.P.A. 1971)(internal citations omitted, italics in original, underlining added).

The emphasis on whether the skilled artisan would be able to recognize without undue experimentation which embodiments encompassed by the claims are inoperative has been echoed in various court decisions. See e.g., *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F. 2d 1569,1577 (Fed. Cir. 1984) (quoting the above-cited passage in *In re Dihn-Nguyen* and even adding that "it is not a function of the claims to specifically exclude...possible inoperative substances...").

In the present case, the skilled artisan would easily recognize any possible unstable heterocycle rings encompassed by the claims and would not attempt to prepare them. Indeed, the Examiner, presumed by the courts to be a person of ordinary skill in the art, has readily recognized what he believes represent inoperative embodiments within the scope of the claims. See e.g., *In re Lee*, 277 F.3d 1338, 1345 (Fed. Cir. 2002) (holding that both the Examiner and the Patent Board of Appeals are presumed to act from the viewpoint of a person having ordinary skill in the art to which the subject matter pertains). Practicing the full scope of the claimed invention,

therefore, would not entail undue experimentation. Therefore, this rejection should now be moot.

The Examiner further argues that "some definitions of heterocyclic [radicals in the art] include B, P and As atoms," apparently implying that Applicant's definition of heteroaryl may or may include those atoms. The Examiner is reminded that the present claims recite only O, N, and S as heteroatoms in the definition of heteroaryl. See claims 1 and 22.

In summary, the meaning of "heteroaryl" is sufficiently clear that the skilled artisan would easily be able to determine the metes and bounds of the term heteroaryl. Furthermore, the specification clearly provides support for such definition (p. 8 lines 26-35) and provides numerous instances of heteroaryl radicals (p. 8 line 35 to p. 9 line 20) that exemplify the above-mentioned definition. Accordingly, Applicants respectfully request that this rejection be withdrawn.

V. Claims withdrawn under 37 C.F.R. § 1.475

The Examiner withdrew claims 11, 12, 18, 19, 22 and 23 allegedly for being directed to more than one utility. Applicants respectfully disagree.

One of the utilities of the claimed invention is the treatment of diseases associated with low cGMP levels, or disorders for whose therapy or prophylaxis an increase in the cGMP levels is desired. Specification at p. 16, lines 16-33. Because several diseases fall within this category, the Examiner believes that Applicants are contravening the unity of invention requirement of 37 C.F.R. § 1.475 by having claims directed to the treatment of more than one disease. Under this belief, the Examiner is

requiring that Applicants elect a single disease from among the current method-of-treatment claims. Applicants respectfully traverse this argument for the reasons of record. However, with the sole purpose of expediting prosecution, Applicants have dealt with the Examiner's objections by presenting new claims 24-26 drawn to the treatment of a single disease (angina pectoris). Therefore, the Examiner's argument is now moot and Applicants respectfully request that this objection be withdrawn.

Applicants respectfully request that the Examiner re-join claims 11, 12, 18, 19, 22 and 23 for examination, since the product of claim 1 should be allowable. Re-joinder of claims 11, 12, 18, 19, 22 and 23 is appropriate according to MPEP § 821.04, which states "if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined." Applicants remind the Examiner that this re-joinder rule by its very nature applies even if there were a legitimate basis to withdraw the claims from consideration in the first place. If the Examiner declines to re-join the claims, Applicants respectfully request that the Examiner explain why that decision would be consistent with the re-joinder provision cited above.

Conclusions

In view of the foregoing amendments and remarks, Applicants respectfully request the examination of this application and the timely allowance of the pending claims.

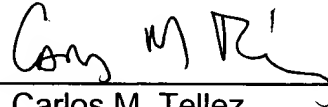
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If there is any fee due in connection with the filing of this Preliminary
Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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Enclosure: Copy of Information Disclosure Statement filed on February 13, 2003, for
Examiner's consideration of Abstracts of foreign-language references.
(7 pages)

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